

REMARKS

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. Claim 1 has been amended to further clarify the invention. New claims 20 to 22 have been added. Support for the amendment and new claims are found throughout the specification, including at page 8, lines 11 to 15. Applicants submit the Amendment raises no issues of new matter.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1-3 and 19 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. The Examiner contends that the scope of “nitric oxide donors” in the claims is not commensurate with the scope of enablement in the disclosure. The Examiner acknowledges at page 2, paragraph 1, of the office action dated April 27, 2005, that the specification is “enabling for an NO donor compound such as SIN-1, SNAP, sodium nitrite, and nitroprusside”.

To meet the enablement requirement of 35 U.S.C. §112, first paragraph, a specification must contain a sufficient description to enable one skilled in the art to make and use the claimed invention (*See, e.g., Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); MPEP §2164.01). A specification does not need to explicitly disclose every detail, and may omit what is well known in the art (*In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); MPEP 2164.01). Applicant respectfully asserts that amended claim 1 is enabled. Amended claim 1 now recites a method comprising administering a compound comprising an inorganic nitrite, a syndoimine, a nitroprusside, a S-nitrosothiol, or mixtures thereof. SIN-1, SNAP, sodium nitrite, and nitroprusside are representative compounds belonging to the syndoimine, S-nitrosothiol, inorganic nitrite and nitroprusside genera of NO donors, respectively. The specification discloses a species of NO donor from each of the claimed genera of compounds.

Although syndoimines, S-nitrosothiols, inorganic nitrites, and nitroprussides are structurally different, they all act intracellularly by a common molecular mechanism. These genera of NO donors have been characterized in terms of their chemical, biochemical, and

pharmacological properties and have been used for the treatment of various conditions. At the time of filing, these genera of compounds were known, and the species disclosed in the specification were known to be species of these genera of compounds, *see, e.g.*:

- Noack, E. and Feelisch, M., "Molecular Mechanisms of nitrovasodilator bioactivation", *Basic Res. Cardiol.* (1991) 86: 37-50.
- Bauer et al., "Nitric Oxide Donors: Biochemical Pharmacology and Therapeutics" in *NITRIC OXIDE: BIOCHEMISTRY, MOLECULAR BIOLOGY AND THERAPEUTIC IMPLICATIONS* 360-381 (Ignarro and Murad, eds., 1995).
- Feelisch, M. "The use of nitric oxide donors in pharmacological studies", *Naunyn-Schmiedeberg's Arch. Pharmacol.* (1998) 358: 113-122.

As such, examples of each genus of compounds would enable a person of skill in the art to make and use the claimed method from the disclosure in the specification.

For at least this reason, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

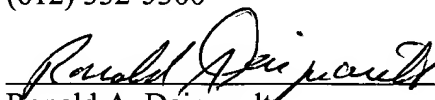
CONCLUSION

In view of the above amendments and remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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